SECTION 5: 510(k) SUMMARY
(as required by section 807.92(c))

AUG 14 2012

A. Submitter's Information:

Name:	Thomas Medical Products, Inc.
Address:	65 Great Valley Parkway Malvern, PA 19355
Telephone Number:	610.651.5000
Facsimile:	610.651.5003
Contact Person:	Tim Stoudt
Title:	Regulatory Affairs Manager
Date Submission Prepared:	January 11, 1012

B. Device Information:

Trade name:	Coronary Sinus Guide & Lateral Vein Introducer Kits
Classification Name(s):	Catheter Introducer (21 CFR §870.1340)
Common or usual name(s):	Coronary Sinus Guide & Lateral Vein Introducer Kits

C. Legally marketed device to which equivalence is claimed:

(a) Thomas Medical Products, Inc. – SafeSheath Coronary Sinus Guide & Lateral Vein Introducer Kits (k003731)
(b) Merit Medical Systems, Inc. - Impress Radiology Catheter (k053171)
(c) Biotronik, Inc. – ScoutPro ACS Coronary Sinus Lead Introducer System (k101776)

D. Description of changes:

The reason for this submission is due to improvements made to the SafeSheath Coronary Sinus Guide & Lateral Vein Introducer Kits designed to provide greater protection against environmental factors known to degrade polymers. The specific changes are:

Element of modification	Predicate device k003731	Modified device	Reason for modification
UV Stabilization	None	0.15 – 0.20% Tinuvin 783 w/w	To provide UV stabilization.
Heat Stabilization	None	0.08 – 0.12% Irganox 1010 w/w	To provide long-term thermal stabilization
RO tip material	Pebax 4033 w/ 80% M10 W	Pebax MX-1205 w/80% C5 W	Material optimization to provide greater stability against degradation.

E. Description of the device:

The Thomas Medical Products, Inc. (TMP) Coronary Sinus Guide & Lateral Vein Introducer Kits (CSG/LVI) are intended to access the coronary venous system. either alone or in a telescopic assembly with other introducers. The CSG/LVI Introducers serve as a conduit to guide devices, including guidewires, pacemaker or defibrillator leads, and catheters, or to deliver contrast medium into specific branches of the coronary venous system. CSG/LVI introducers are intended to introduce left ventricular leads through their lumen. They have direct contact to the inner heart. CSG/LVI introducers come with various curve configurations and lengths to facilitate access to the coronary sinus OS and sub-selective access to angulated lateral vein branches. CSG/LVI introducers are designed as single use devices and for short

term application (< 24 hours). Only medical doctors and medical personnel, who are well trained in cardiology, should apply these introducers.

The Coronary Sinus Guide Introducer has a peel-away sheath with break-away hemostasis valve. The Lateral Vein Introducer has a break-away hub with integrated handle that requires no cutting and provides a secure grip during slicing, reducing the risk of lead displacement.

The Lateral Vein Introducers have a shaft design with three (3) gradually decreasing stiffness segmentations from proximal to distal. The shaft is reinforced by a metal braid from the proximal end until approximately 0.175 inch from the distal end. The shaft is coated by a medical-grade coating that provides enhanced lubricity when advanced through the Coronary Sinus Guide Introducer.

The proximal end of the CSG/LVI Introducers are equipped with a hemostasis valve that reduces the risk of blood loss and air embolism and a side-port with 3-way stopcock to allow fluid infusion and contrast injection.

There are differing various versions of the introducer curves that are used according to the anatomy of the present coronary vasculature. The distal soft tip has a tapered outer diameter and the distal tip further contains a polymeric x-ray marker for enhanced visibility under fluoroscopy.

Package contents (Coronary Sinus Guide Introducer Kit):
- One (1) Coronary Sinus Guide Introducer
- One (1) P.T.F.E. coated guidewire
- One (1) Curved braided guiding core or non-braided guiding core
- One (1) Straight vessel dilator
- One (1) Transvalvular Insertion Tool (T.V.I.)
- One (1) 18 g XTW needle
- One (1) 12 cc syringe

Package contents (Lateral Vein Introducer Kit):
- One (1) Lateral Vein Introducer
- One (1) Transvalvular Insertion Tool (T.V.I.)
- One (1) Slicer
- One (1) Target Vein Selector – Merit Impress Radiology Catheter, k053171

F. Intended use of the device:

Coronary Sinus Guide & Lateral Vein Introducer Kits are indicated for the introduction of various types of pacing or defibrillator leads and catheters.

G. **Summary of the technological characteristics of the device compared to the predicate devices:**

Features	UV & Heat Stabilized CSG/LVI kits	Non-UV & heat stabilized CSG kits - k003731	Merit Impress Radiology Catheter k053171	Biotronik ScoutPro ACS CS Lead Delivery System k101776
Hemostasis valve provided	Yes	Yes	No	Yes
Compatible with .038" guide wire	Yes	Yes	Yes	Yes
Lengths: 40 to 50 cm / 62 cm	Yes	Yes / No	No	Yes
French sizes: 9 F I.D / 7 F I.D.	Yes	Yes / No	No	No
Curves: 0 to 180 degree, single or compound curves	Yes	Yes	Yes	Yes
Peel-away CSG sheath with break-away hemostasis valve	Yes	Yes	No	No
Wire braid reinforcement completely encapsulated (LVI & Braided Cores)	Yes	No	Yes	Yes
Radiopaque tip or marker	Yes	No	Yes	Yes
Side port for infusion and contrast injection	Yes	Yes	No	No
UV & heat stabilizers	Yes	No	No	Unk

H. **Summary of testing:**

	Test Description	Results
Biocompatibility		
Product applicability: Coronary Sinus Guide & Lateral Vein Introducer components w/ UV and heat stabilization		
Test Sample: XD-3050-00, Gen. III CSG Sheath, Lot 36564 (**proposed device**)		
	USP Pyrogen Study, Material Mediated	Pass, non-pyrogenic
	Cytotoxicity Study using the ISO elution method	Pass, < grade 2
	ISO Maximization Sensitization Study - Extract	Pass, not considered a sensitizer
	ISO Intracutaneous Study, Extract	Pass, control/test Δ <1.0
	ISO Systemic Toxicity Study - Extract	Pass, no mortality or evidence of systemic toxicity
	ASTM Hemolysis	Pass, hemolytic index = 0.0%
	Physicochemical testing using an alternative extract - complete	Pass
	USP Physicochemical Testing – Plastics - Complete	Pass, meets USP limits

	Test Description	Results
Biocompatibility (continued)		
Product applicability: Lateral Vein Introducer and braided core components		
Test Sample: Printed braided Pebax tubing - XD-2186-04 (**representative sample of proposed device**)		
	L929 MEM Elution Test	Pass, Grade 0
	Kligman Maximization Test - ISO	Pass, Grade 1
	Intracutaneous Injection Test - ISO	Pass, considered negligible irritant
	Systemic Injection Test - ISO	Pass, considered negative
	Hemolysis – Rabbit Blood - ISO	Pass, 0.0% hemolysis

	Test Description	Results
Simulated Use Testing		
Coronary Sinus Guide & Lateral Vein Introducer		
Test Sample: FCL-156-00 (LVI)/FDL-050-00 (BC)/XD-3050-00 (CSG) - **proposed devices**		
	Sheath separation (CSG only)	Pass
	Hub break force	Pass

	Test Description	Results
Physical/Dimensional Testing		
Coronary Sinus Guide & Lateral Vein Introducer		
Test Sample: FCL-156-00 (LVI) FDL-050-00 (BC)/XD-3050-00 (CSG) - **proposed devices**		
	Tip pull test	Pass
	Tip integrity test	Pass
	Bend-back testing	Pass
	Joint interface length (CSG only)	Pass
	Hub pull force	Pass
	Tip I.D.	Pass

I. **Substantial equivalence rationale:**

Thomas Medical Products, Inc. considers the Coronary Sinus Guide & Lateral Vein Introducer Kits substantially equivalent to the currently marketed predicate devices. This assessment is based upon analysis of similar technological characteristics, bench testing, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 14 2012

Thomas Medical Products, Inc.
c/o Mr. Timothy Stoudt
Regulatory Affairs Manager
65 Great Valley Parkway
Malvern, PA 19355

Re: K120158
Trade Name: Coronary Sinus Guide and Lateral Vein Introducer Kits
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: II (two)
Product Code: DYB
Dated: July 30, 2012
Received: July 31, 2012

Dear Mr. Stoudt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510(k) Number (if known): K120158

Device Name: Coronary Sinus Guide & Lateral Vein Introducer Kits

Indications For Use:

For the introduction of various types of pacing or defibrillator leads and catheters.

Prescription Use X AND/OR Over-The-Counter-Use
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(Optional Format 11-13-03)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120158